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May 20, 2016

By ECF

Honorable Margo K. Brodie, U.S.D.J.
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: Greene v. Gerber Products. Co., Case No. 16-cv-01153 (MKB)(RER)

Dear Judge Brodie:

We represent Defendant Gerber Products Co. (“Gerber”) in the above-styled action and write pursuant to Rule 3.A of Your Honor’s Individual Practice and Rules to request a conference regarding Gerber’s proposed motion to dismiss Plaintiffs’ Complaint. The allegations in the Complaint are nearly identical to the allegations in *Hasemann v. Gerber Products Company*, Case No. 15-cv-02995 (MKB)(RER), also before Your Honor. Accordingly, Gerber relies in part on its letter of August 14, 2015 filed the *Hasemann* action (Dkt. No. 8) as well as Gerber’s motion to dismiss filed in the *Hasemann* action (Dkt. Nos. 23 and 25).

Plaintiffs here assert statutory claims under the Ohio Consumer Sales Practices Act (Ohio Rev. Code Ann. §§ 1345.01 *et seq.*) (“OCSPA”), the Ohio Deceptive Practices Act Ohio Rev. Code Ann. §§ 4165.01 *et seq.* (“ODTPA”) and North Carolina Unfair & Deceptive Trade Practices Act N.C. Gen. Stat. Ann. §§ 75-1.1 *et seq.* (“NCUDTPA”). Plaintiffs seek certification of Ohio and North Carolina subclasses. In addition, Plaintiffs allege claims of fraudulent concealment, intentional misrepresentation, negligent misrepresentation and unjust enrichment. Plaintiffs seek certification of a nationwide class based on the four common law claims.

II. The Complaint Fails To Allege That Gerber’s Efficacy Claims Were False

Plaintiffs’ conclusory allegations in the Complaint fail to allege a sufficient factual basis to state a claim that Gerber’s representations regarding the efficacy of Good Start are false under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (U.S. 2009). *See also Kardovich v. Pfizer*, 2015 WL 1506996 (E.D.N.Y. March 31, 2015) (finding plaintiff’s misapplication of documents cited in complaint to be conclusory and insufficient to meet the plausibility standard articulated in *Iqbal*).

Plaintiffs’ claims allege or otherwise assert fraud and are therefore subject to a heightened pleading standard under F.R.C.P. 9(c). In *Ferron v. SubscriberBase Holdings, Inc.*, 2009 WL 650731 (S.D. Ohio 2009), the court applied a heightened pleading standard for claims

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under the OCSPA because “deceptive trade practices, are, at their core, fraud claims.” *Id.* at *5, n. 4 (citing *Ferron v. Zoomgo, Inc.*, 2007 WL 1974946 (S.D. Ohio July 3, 2007)) *Id.* at *5. The same applies to claims brought under the NCUDTPA. *see also Topshelf Management, Inc. v. Campbell-Ewald Co.*, 117 F. Supp. 3d 722, 731 (M.D. N.C. Aug. 3, 2015) (applying heightened pleading standard to claims alleging detrimental reliance on false or deceptive representations under NCUDTPA).

Like the FTC’s complaint from which Plaintiffs’ allegations were lifted, the Plaintiffs have, at most, pled that Gerber’s alleged claims were inadequately substantiated. Lack of substantiation, however, is the legal standard that applies to certain claims brought by the FTC under the FTC Act, and is insufficient as a matter of law to support a claim for false advertising under state law. Indeed, last year the Fourth Circuit ruled that to state a plausible claim for relief under state consumer protection statutes, “plaintiffs must allege that all reasonable experts in the field agree that representations are false.” *In re GNC Corp.*, 789 F.3d 505, 509 (4th Cir. 2015), *reh’g and reh’g en banc denied*, (4th Cir. July 27, 2015) (affirming dismissal of claims brought under Florida, California, Illinois, **Ohio**, New York, New Jersey and Pennsylvania law). That is far from the case here. By incorporating an FDA letter dated May 24, 2011 (the “2011 Letter”) in their Complaint, Plaintiffs admit that there is evidence supporting the claim that feeding infant formula made from partially hydrolyzed whey protein to infants with a family history of allergy reduces the risk they will develop atopic dermatitis, the most common infant allergy. The 2011 Letter cites numerous scientific materials that support Gerber’s claims regarding Good Start. The FDA clearly concluded “the current scientific evidence is appropriate for consideration of a qualified health claim regarding the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis” Plaintiffs cite the FDA letter for its finding that the science is “uncertain.” (Compl., ¶ 9). That uncertainty (or equivocality among the scientific community) is the reason why the FDA exercised its enforcement discretion. That admission is fatal to Plaintiffs’ claims.

Plaintiffs mischaracterize a June 2011 study in support of their claims in this action. (Compl. ¶ 47). That study did not find that any of Gerber’s claims regarding Good Start were false. Regardless of the conclusions of that study, it is clear based on the FDA’s review of the scientific record that FDA permitted Gerber to make a qualified health claim relating to the use of 100 percent whey-protein partially hydrolyzed infant formula to address concerns relating to infant allergies. To the extent that Plaintiffs have raised an argument that there are competing views within the scientific community, *In re GNC Corp.* makes clear that the existence of such competing views cannot support the Plaintiffs’ bald assertion of falsity.

Plaintiffs’ reliance on the FDA’s Warning Letter is also misplaced – and perplexing – as that letter contradicts rather than supports Plaintiffs’ claims. Indeed, in the letter, the FDA explicitly stated that “the claims on [Gerber’s] product label,” which is attached as Exhibit C to the Complaint, “and [Gerber’s] website asserting the limited evidence linking the benefit between consumption of ‘100% whey partially hydrolyzed’ and atopic dermatitis **are generally consistent with the claims suggested in the 2011 letter announcing the claims for which FDA would consider the exercise of enforcement discretion**” (emphasis added).

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III. Good Start Received A Qualified Health Claim

Plaintiffs likewise fail to state a claim that Gerber misled consumers by representing that Good Start “meets the criteria for a FDA Qualified Health Claim for atopic dermatitis.” (*See* Compl., Ex. B). The Complaint concedes – as it must – that in the 2011 Letter, the FDA did in fact approve a qualified health claim for Good Start regarding atopic dermatitis. (Compl., ¶ 32). After reviewing the available scientific evidence in support of Gerber’s petition for a qualified health, the FDA concluded that “the current scientific evidence is appropriate for consideration of a qualified health claim regarding the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis....” (Compl., Ex. B, 2/19). The allegations in the Complaint are flatly contradicted by the 2011 Letter, which establishes unequivocally that Good Start did in fact satisfy the FDA’s criteria for a qualified health claim for atopic dermatitis. That is the very reason why the FDA decided that it would exercise its enforcement discretion (*i.e.*, not take enforcement action). Because Gerber met the FDA’s criteria for a qualified health claim, Plaintiffs fall far short of meeting the criteria for properly alleging a claim for false advertising. In order to sustain an action for false advertising, a private plaintiff must make plausible allegations and ultimately prove that the advertised claims are actually false. All that Plaintiffs do here is conclude that Gerber’s claims are false. Such an allegation does not meet the plausibly standard. *Iqbal*, 556 U.S. at 664.

IV. The Notice Requirement of the OCSA Is Lacking

A consumer cannot file a class action under the OCSA unless the consumer’s claims meet the notice requirement of Ohio Rev. Code Ann. §§ 1345.09(B). *See Phillips v. Philip Morris Companies Inc.*, No. 5:10-cv-1741, 2013 U.S. Dist. LEXIS 40908 (N.D. Ohio Mar. 21, 2013), *17-18. Plaintiffs’ attempt to plead notice fails (Compl., ¶¶ 98-100), because the purported notice alleged in the Complaint: (1) is based on **consent orders** negotiated between litigants, not on judicial findings by an Ohio court; and (2) have nothing whatsoever to do with the relationship between 100% whey protein partially hydrolyzed and atopic dermatitis.

V. Consumers Cannot Claim Under The ODTPA

Relief under the ODTPA is not available to consumers. *Phillips v. Philip Morris Companies Inc.*, No. 5:10-cv-1741, 290 F.R.D. 476, 484 (N.D. Ohio 2013), (holding after a reasoned analysis “consumers lack standing to bring claims under the DTPA”).¹

VI. Conclusion

Accordingly, Gerber respectfully requests that the Court schedule a pre-motion conference.

¹ Here, Plaintiff Wilkerson likewise makes a general claim under the NCUDTPA and makes a blanket claim that Gerber’s advertising proximately caused her injury through an “inflated premium” (Compl., ¶ 116), but does not bother to allege how Gerber Good Start was worth less than what she paid for it. *Walker v. Sloan*, 137 N.C. App. 387, 395, 529 S.E.2d 236, 243 (2000).

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Respectfully submitted,

/s/ David I. Zalman

David I. Zalman

cc: All Counsel of Record (*via* ECF)